

Guidelines for development and use of transluminally placed endovascular prosthetic grafts in the arterial system

Frank J. Veith, MD, William M. Abbott, MD, James S. T. Yao, MD, PhD, Jerry Goldstone, MD, Rodney A. White, MD, Dorothy Abel, BS, Michael D. Dake, MD, Calvin B. Ernst, MD, Thomas J. Fogarty, MD, K. Wayne Johnston, MD, Wesley S. Moore, MD, Arina van Breda, MD, George Sopko, MD, Paul Didisheim, MD, Robert B. Rutherford, MD, Barry T. Katzen, MD, and D. Craig Miller, MD, *for the Endovascular Graft Committee**

The feasibility of placing prosthetic grafts within the arterial tree by inserting them via a remote site, guiding them intraluminally to the appropriate location, and fixing them there with attachment systems, such as a variety of expandable stents, has been demonstrated in animals and human beings.¹⁻³ There is a potential for these transluminally placed endovascular grafts (TPEGs)^a to provide improved treatment for a variety of arterial lesions, including aneurysms, traumatic injuries, and arteriosclerotic occlusions, and TPEG repairs of all three kinds of lesions have been carried out at various levels of the arterial tree with short-term success.^{1,4-17} Because TPEG repairs can be performed less invasively, their

risks and costs may be less than those of standard vascular graft operations. They will therefore be extremely attractive to both patients and physicians, and consequently there will be enormous pressure to develop and use these devices rapidly.

The purpose of this document is to foster the development of safe, effective devices for performing TPEG repairs of various arterial lesions at all levels of the arterial tree. To this end, it will provide guidelines for the careful and structured evaluation and monitoring that are necessary to document the safety, efficacy, and effectiveness^b of these devices in various settings before they undergo widespread clinical use. Although these guidelines are not a regulatory document, they are intended to help avoid premature and potentially harmful usage of TPEGs.

GENERALITIES

Types of TPEGs

TPEGs can be divided into those that are *covered single stent devices*^c and *end fixation devices*, which

*See appendix.

The opinions expressed are those of the authors and do not reflect those of the United States Food and Drug Administration, the Department of Health and Human Services, or the Public Health Service.

Reprint requests: Frank J. Veith, MD, Department of Surgery, Montefiore Medical Center, 111 E. 210th St., New York, NY 10467.

J VASC SURG 1995;21:670-85.

24/9/62969

^aAt present, these include a variety of graft-stent combinations. However, these guidelines apply to other devices that will have or develop blood impervious walls and that may be inserted via intraluminal routes to provide prosthetic support or replacement of a diseased arterial wall. Devices that involve autologous tissue (e.g., stents and a vein graft) are also a variety of TPEG. Another variety is TPEGs used in the systemic or portal venous systems. Although some generalities in these guidelines apply to these autologous and venous TPEGs, they will not be dealt with specifically in this document. Throughout these guidelines the terms *TPEG*, *stented graft*, and *stent graft* are used interchangeably, although it is recognized that TPEG has a broader meaning because not all of these devices will necessarily include a stent component per se.

^b*Safety* is defined as freedom from complications or intrinsic device failure; *efficacy* is defined as the ability of the device to restore the vascular wall and luminal integrity, to prevent aneurysm expansion and rupture, or to maintain luminal patency; and *effectiveness* is defined as the ability to extend patient survival and limb or organ function by preventing aneurysm expansion and rupture or by maintaining arterial flow through the diseased segment of the artery.

^cA covered single stent is one to which a prosthetic graft, which is or will become impervious to blood, is fixed so that the graft covers a portion or all of the internal or external surface of the stent after its expansion within a blood vessel. Some devices of this variety may incorporate stentlike components within a graft matrix to provide an *integrated unit*; others may consist of a stent alone that becomes impervious to blood.

comprise a prosthetic graft fixed with a stent or other attachment system at both ends. Variants of the latter are bifurcated Y grafts or branched grafts with attachment devices at all three ends and long grafts stented at one end and with no stent or a suture anastomosis at the other end. Further division of TPEGs can be based on the *characteristics of the device*, specifically the nature of the *delivery system* (e.g., sheath/no sheath, over a wire/not over a wire, etc.), the nature of the *attachment or fixation system and method* (balloon-expandable, spring-expandable, or mechanically expandable stent or other device, with or without hooks for fixation to the vessel wall, and the nature of the *graft or covering material component* (knitted polyester [Dacron],^d woven polyester [Dacron],^d polytetrafluoroethylene [PTFE] or other developmental prosthetic material).

Usage categories

Because different characteristics and properties of TPEGs may be required to treat different forms of arterial disease in different parts of the arterial tree, usage must be defined on the basis of *lesion location* and *lesion pathology*. Safety, efficacy, and effectiveness must at least be considered separately for each device and each usage. This document provides guidelines for evaluating TPEGs according to usage categories defined by the following vessel sizes and locations: the *thoracic and suprarenal aorta, large arteries* (infrarenal aorta, iliac, innominate, common carotid and subclavian), and *medium-sized arteries* (femoral, popliteal, axillary, visceral, renal, coronary,^e vertebral,^e and carotid bifurcation and branches^e); and for devices to be used to treat *aneurysms, traumatic lesions* (false aneurysms, arteriovenous fistulas, mural injuries), *stenotic and occlusive lesions*, and *dissections and intramural hematomas*.

Usage categories other than these may be required on the basis of pathologic, anatomic, or physiologic characteristics of the patient or lesion being treated. For example, some aneurysmal, traumatic, or ulcerating atherosclerotic lesions may cause distal embolization as their only manifestation. The

suitability of such lesions for TPEG treatment might need to be evaluated separately.

For purposes of demonstrating safety, efficacy, and effectiveness, each specific device should be considered for evaluation in a specified-sized artery in one or more locations with similar defined disease. However, it is possible that a given device will be safe and effective in several different sized arteries, in different locations, and even for the treatment of different types of lesions. Accordingly, it will be acceptable to evaluate and demonstrate safety, efficacy, and effectiveness of a given device by studies in which that device is used in more than one location or for more than one type of lesion. In such circumstances a satisfactory rationale and justification for combining usage categories must be provided. All studies should be designed to demonstrate statistically valid conclusions within one or more subdivisions of this categorization system.

Requirements for developmental and testing centers

Because TPEGs require vascular surgical skills and catheter-guidewire-imaging skills to insert and deploy, the clinical teams involved in their development and initial testing in patients should consist of individuals with the highest levels of expertise in both of these modalities.^f This means that individuals possessing skills and experience in vascular surgery^g and interventional radiology must be involved in and responsible for the efforts of these developmental centers. Usually this combination of skills will require two or more individuals, a vascular surgeon and an interventional radiologist who work smoothly together as a team, although it is possible that one individual will possess the requisite skills and experience to perform all parts of the procedure. It is recommended that developmental or research centers testing these devices be staffed by integrated teams of vascular surgeons and radiologists, coordinated by a single individual who is familiar with vascular disease and natural history and all standard treatment alternatives and who bears overall patient responsibility. To deal optimally with unexpected problems, proce-

^dDacron is a trademark of DuPont Co., Inc., Wilmington, Del. It refers to the polyester, polyethyleneterephthalate. Throughout these guidelines the generic term, *polyester*, will be used for this material.

^eCoronary, carotid, and vertebral devices will have special problems relating to the end organs they supply and technical challenges to obtain access. Appropriate monitoring of end organ function, that is, the heart or brain, will be required with devices used in these arteries.

^fSeparate training and credentialing guideline documents for individuals who can perform vascular surgery and endovascular procedures have been prepared by various specialty organizations.¹⁸⁻²³ The general principles expressed in these documents should also apply to this guideline document.

^gProcedures performed for lesions of the thoracic aorta may require the participation of individuals skilled and credentialed in cardiothoracic surgery, especially if it appears that cardiopulmonary bypass may be necessary to manage device complications.

dures carried out on patients should be performed in a procedural room that is equipped with digital imaging fluoroscopy and that has all the appropriate equipment and personnel to carry out open arterial operations. In light of current designs, approaches, and clinical experience and because the possibility that large artery injury, occlusion, or rupture may require immediate emergency operation, procedures conducted on the thoracic or abdominal aorta, the iliac arteries, or other aortic branches should be performed in a room that has appropriate imaging devices and equipment and staff to carry out emergency major vascular or cardiovascular surgery. (See the section on "Requirements For Facilities in Which TPEGs Will Be Used Clinically" for further details regarding equipment requirements.)

In addition, these centers should have inpatient radiologic and vascular surgical services experienced in performing the full range of standard arteriography, catheter-directed angioplasty and stent placement, and all vascular and cardiothoracic operations. They should also have the outpatient facilities, noninvasive vascular diagnostic laboratories, radiology services, and support staffs to perform the high-quality imaging techniques needed for accurate and thorough patient follow-up evaluation. Centers involved in these studies must demonstrate a commitment to long-term follow-up.

Comparison between TPEGs and standard arterial grafts and stents

It should be recognized that some properties of TPEGs may differ from those required of standard grafts or stents used to treat similar lesions in similar locations. Because TPEGs will be inserted from a remote site and guided into position, there are clear advantages to reducing their unexpanded cross-sectional diameter or "profile" as much as possible. In this way the requirement that they be introduced through an open arteriotomy in a large-caliber artery will be minimized. Thus devices with a low profile offer clear advantages in terms of feasibility and applicability. However, making the TPEG thin and flexible to achieve a low, unexpanded profile may require a thinner graft with reduced strength.

Currently it is not known whether TPEGs need the same burst strength or porosity characteristics as a standard arterial graft. A TPEG that will be placed within the unsupported lumen of an aortic aneurysm must have adequate strength and durability to withstand aortic pressures and flows, although it may not have to meet the same safety factors required of stan-

dard aortic grafts with regard to these parameters. In addition, a TPEG intended for use in the treatment of unruptured aneurysms may not require the same porosity specifications as a standard graft used to treat the same condition. Because the endoluminally inserted device will be contained within the intact aneurysm sac, greater porosity may be tolerable because transinterstitial bleeding will be contained by the aneurysm wall until fibrin deposition occludes the pores. Moreover, a TPEG placed within a stenotic or occluded artery may receive structural support from the surrounding arterial wall, thereby allowing the use of grafts with different physical properties (e.g., decreased wall thickness and strength). Long-term experimental and clinical studies will be required to settle these issues. In contrast, some endoluminally placed grafts may require unusual characteristics not needed with standard grafts. Examples include physical properties that contribute to an intact and fixed friction seal at junction points with host arteries, to developing rapid and secure impermeability to blood in ruptured aneurysms and traumatic arteriovenous fistulas, or to resisting compression when a TPEG is placed within occluded arteries.

DEVELOPMENTAL STUDY PROTOCOLS

When TPEGs and appropriate systems for their insertion are developed and are believed to be suitable for treatment of specific lesions in specified locations, the following general guidelines are recommended for preclinical and clinical testing *before* the devices are brought into widespread usage. For any device, the evaluation must consist of four phases: bench testing, (structural/mechanical), preclinical (animal) testing, clinical testing-feasibility, and clinical testing-comparative performance. However, in identifying appropriate testing for any device, consideration must be given to the mode(s) of failure and its/their effect on the performance of the device.

Bench testing

For the *graft portion* of the device, this should consist of essentially the same tests of physical properties, such as strength, durability, porosity, kink resistance, suture holding ability,^h flexibility, and longitudinal and radial stretchability, as are required for a currently standard or proposed new arterial prosthesis.²⁴⁻²⁶ The possibility also exists that modified requirements may need to be developed for new graft materials that may be developed and used for

^hIf an open surgical anastomosis may be required at one end.

TPEGs. In addition, the *stent portion* or *attachment system* of a TPEG device will have to be evaluated for the various characteristics important to its function, such as inertness in blood, lack of toxicity, absence of metal fatigue, flexibility, compression resistance, and other physical properties that contribute to a leak-proof seal and secure fixation at junction points with arteries.²⁷ Finally, the *delivery system* of a device will require bench testing to demonstrate appropriate maneuverability, kink resistance, radiopacity, and marker visibility to be effective in the clinical setting in which it will be used.

Animal testing

Successful animal implantation of all TPEG devices, by use of the same introduction systems and localization and deployment methods that will be used in patients, should be required before clinical trials can be undertaken. Successful implantation includes the ability to visualize and deploy the device by techniques similar to those that will be required in patients; the firm fixation of the device at the site of original implantation; and acceptable freedom from leakage, migration, vessel wall erosion, thrombosis, excessive intimal hyperplasia with luminal narrowing, and distal embolization. There should also be acceptable freedom from other complications related to the fixation component or stent, particularly those with hooks or spikes. The duration of observation in animal testing should be for a minimum of *6 months* before clinical tests can be undertaken. Longer studies may be needed if synthetic materials not currently in use in the vascular system are involved.

The TPEG should be inserted in animal models at similar although not necessarily identical anatomic locations to those intended for use in patients. Every effort should be made to use animal models that mimic as closely as possible the clinical problem being addressed. Device insertion techniques and end-points studied should parallel those that will apply in the clinical setting as much as possible. Imaging techniques, such as angiography or intravascular ultrasonography (IVUS), that provide visualization and localization of the fixation device and the graft are important parameters to evaluate in these studies.

It is recognized, however, that animal models have several limitations in evaluating TPEGs. First, the commonly available large animal models (dogs, pigs, or sheep) have arteries that are smaller than comparable arteries in human beings. Calves are larger, and their arteries better approximate the size of human arteries, but their rapid growth limits their utility for anything other than short-term studies.

Second, it is not possible to produce in animals arterial lesions that are comparable to those in patients, with the possible exceptions of traumatic arteriovenous fistulas, false aneurysms, and aortic dissections.²⁸ Although animal models with fusiform polyester cloth aneurysms have been described^{2,3,29,30} and have some limited applicability, good models of true aneurysms and arteriosclerotic occlusive disease do not exist. Accordingly, animal studies have limited applicability in predicting the outcome of TPEGs in treating some human arterial lesions. Furthermore, it may be necessary to test some devices in more than one animal model to address all concerns (e.g., long-term implants in dogs with acute studies in calves to study clinical-sized devices). All animal studies should include gross and histologic evaluation and, if possible, angiographic evaluation, computed tomography (CT) scanning with contrast, magnetic resonance imaging (MRI), and/or IVUS to document device, luminal, and arterial wall structure and relationships.

All the animals involved in these studies must receive humane care in compliance with the "Principles of Laboratory Animal Care" formulated by the National Society for Medical Research and the *Guide for the Care and Use of Laboratory Animals* (NIH Publication No. 86-23, revised 1985) prepared by the National Academy of Sciences.

Clinical testing

Clinical testing must demonstrate the safety, efficacy, and effectiveness of TPEGs in the treatment of human arterial diseases. Separate studies may be needed for each usage category and each artery size and lesion described in the "Generalities" section. However, it is possible that some devices will be suitable for treating multiple categories of lesions. Therefore it may be appropriate to combine lesion sites and pathologic categories for clinical testing when this can be supported and justified. This is particularly likely when treatment of uncommon lesions is being considered. Clinical testing will be divided into two phases: feasibility testing and comparative performance testing.

Feasibility testing. This should demonstrate that insertion of a TPEG device is possible in a given disease state in a given location and that the device functions safely and effectively for at least *6 months*. These tests must include comparative preprocedural and postprocedural noninvasive measurements of the distal circulation and, in the case of aneurysms, their size before and 3 and 6 months after TPEG placement. These measurements include lower extremity

segmental systolic pressures and pulse volume recordings (or Doppler waveform measurements) and ultrasound, contrast-enhanced CT scanning, MRI, and/or IVUS measurements of aneurysm size.ⁱ They must be available in at least 10 patients and should be supplemented by appropriate imaging studies to demonstrate device patency, confinement of flowing blood to the graft lumen, and freedom from leakage, migration, and aneurysm enlargement.^j Preplacement, completion, and 6 months postplacement arteriographic confirmation should be provided in at least one half of the patients and preferably in all. However, if other less invasive modalities can provide accurate equivalent information, arteriographic study may be unnecessary.

There are two types of *feasibility studies*. In both, protocols should be consistent with Institutional Review Board (IRB) and Food and Drug Administration (FDA) standards and regulations.

In the first type of feasibility study, *standard usage*, the TPEG treatment is offered to patients who are candidates for standard operative abdominal aneurysm repair,²⁵ standard operative graft or balloon angioplasty/stent treatment of occlusive lesions, or standard surgical repair of traumatic lesions or peripheral aneurysms for the usual indications. In this setting, the patient must be prepared for and willing to undergo the standard procedure if the TPEG placement is impossible or unsuccessful or has a complication. In general, if the aorta or iliac arteries are involved or if limb salvage is the indication, patients having these initial TPEG procedures should have them performed in a location that is equipped and staffed for emergency operative repair.

In the second form of feasibility study, *high-risk usage*, patients who are unsuitable for or at high risk for the standard treatment may be offered the new TPEG treatment as an option.^k In the case of abdominal aneurysm repair, these can be patients with large, threatening aneurysms whose operative risk is excessive, for example, in excess of 3 to 4 times

normal, on the basis of heart, lung, or liver disease or previous abdominal scarring or infection.³¹ In the case of occlusive lesions or peripheral aneurysms, the same risk factors and the presence of limb-threatening ischemia or a large aneurysm could be considered an indication to offer TPEG placement as a therapeutic option.

Comparative performance testing—clinical trials. This phase of evaluation is designed to show that the TPEG device will perform essentially equivalent to or significantly better than standard treatment. There are several ways to test safety, efficacy, and effectiveness and to show equivalence or superiority. It is not the purpose of this document to specify how a clinical trial of a new TPEG device should be designed and conducted. This has been discussed in a recent editorial.³² However, such trials should be conducted in a fashion that is scientifically sound and that provides statistically valid data relating to the important criteria to be described below for the various usage categories. When it is feasible and appropriate, these studies should be designed to permit a valid comparison of the safety, efficacy, and effectiveness of a new TPEG device and current standard treatment(s) of similar arterial lesions in similar patients. In other circumstances, when it may not be feasible or in the interests of patients to obtain such valid comparative performance data the clinical trial study protocol should clearly indicate the reasons for this and provide an acceptable alternative method for testing the hypotheses posed in the study and documenting the new TPEG device's safety, efficacy, and effectiveness.^l

Those responsible for the clinical trials of new TPEG devices should consult the appropriate office at the FDA (Office of Device Evaluation) *before* the design and conduct of a trial. By doing so, the investigator will become familiar with the FDA's requirements and recommendations for premarket approval of a new medical device and how to design an appropriate trial that is likely to yield valid conclusions about the clinical performance of the TPEG device.

In general, the format recommended throughout

ⁱThese measurements should permit accurate definition of wall, clot, and lumen (flowing blood) dimensions.

^jIn the descending thoracic aorta, transesophageal echo may be useful for these evaluations.

^kThere is some disagreement over the ethical merits of demonstrating feasibility in patients for whom no surgical rescue procedure is available if the untested device fails. These guidelines cannot resolve this disagreement. Ideally, some prior experience or other evidence should be available to suggest feasibility before high-risk usage of a new TPEG device is undertaken. High-risk usage protocols must have risk factors or criteria clearly defined and objectively documented to avoid overly liberal use.

^lIn some exceptional circumstances in which no satisfactory treatment exists, a high-risk usage study of a TPEG device may constitute appropriate evidence for the manufacturer to obtain approval to market and sell the device for a specific indication. An example would be use of a TPEG device in the treatment of a central arteriovenous fistula or false aneurysm in patients who would otherwise require a thoracotomy or laparotomy for standard surgical repair and in whom intercurrent heart or lung disease precludes general anesthesia or makes its risk prohibitive.

these guidelines will entail a *feasibility study* of at least 10 patients observed for 6 months, followed by a *comparative performance study* with an adequate number of patients in the device test group monitored after the procedure to allow statistically valid comparisons after 1 to 2 years with similar patients with similar stages of the disease process.^m Comparative performance studies should include the primary criteria listed in Table I with regard to procedural (30 day) morbidity and mortality rates and 1 to 2 year device safety and efficacy. The results should allow statistically valid and biologically meaningful conclusions indicating whether a given device provides results that are better than, worse than, or equivalent to standard treatment as measured by these criteria. Demonstration of statistically significant equivalence between two treatment groups may require unacceptably large numbers of patients so that comparative studies should be designed to show statistically significant differences between the TPEG and standard treatment or *essential equivalence*, that is, no grossly apparent difference.

Every effort must be made in all clinical stages of testing to obtain postmortem examination of patients who die of any cause to determine the cause of death and to perform a complete explant analysis including gross and microscopic examination of the device and the sites of device implantation and fixation to determine the structure and histologic condition of the proximal and distal vessel and of the aneurysm or other arterial lesion being treated.

It is recognized that some comparative performance trials may, when appropriately justified, evaluate a specific TPEG device in more than one location or for treatment of more than one type of lesion. However, because device requirements for different lesions and different locations may vary, the crucial data to be collected or criteria for seven distinct major types of trials are described separately in Table I and the following text sections. These seven major types of trials are (1) infrarenal aortic aneurysms (tubular device required); (2) infrarenal aortic aneurysms with no distal neck or with iliac aneurysms (bifurcated device required); (3) peripheral aneurysms (femoral, popliteal, or other); (4) traumatic arterial lesions (false aneurysms, arteriovenous fistulas, or mural injuries); (5) iliac artery (common and external) occlusive disease with or without involvement of the

distal aorta; (6) femoral or popliteal artery occlusive disease; and (7) descending thoracic aortic disease (aneurysms, dissections, and traumatic injuries). Other data that should be collected and analyzed in addition to those listed in Table I are duration of the procedure, time in an intensive care unit, length of hospital stay, and the number of units of homologous blood transfused. Systemic complications of these procedures (defined in Table IIA) and device-related failures or complications (defined in Table IIB) must also be documented and analyzed.

It is possible that other types of clinical trials will be required in other settings or with specific subgroups of patients. These other trials can be based on the seven major types of trials described below.

Abdominal aortic aneurysm (infrarenal) – tubular devices

Adequate data must be collected so that, after a group of patientsⁿ are treated by the TPEG device and compared with standard operative repair with a prosthetic graft, it can be determined that the groups being compared are similar except for the form of treatment.

Preprocedural data should be collected on age, sex, ethnic origin, height, weight, diabetic status, cardiac function and risk factors, pulmonary function and risk factors, hepatic and renal function, hematologic values, lower extremity pulse status and ankle/brachial indexes (ABI), and previous abdominal operations and scars (Table III). CT scanning, MRI, ultrasonography, and/or arteriography should be performed and data acquired with regard to aneurysm length, transverse, and anteroposterior diameters; the extent and dimensions of intraluminal clot and flowing blood; the diameter, length, and degree of calcification of the normal infrarenal aortic segment (i.e., the proximal and distal aortic “neck” or “cuff”); the diameter and tortuosity of the common and external iliac arteries (supplement with diagram); and the location and relationship to the aneurysm of patent renal arteries, lumbar arteries, and the superior and inferior mesenteric arteries. These data may be supplemented by MRI or CT three-dimensional aortic reconstructions showing aneurysm, neck, and branch structure, including a definition of the areas occupied by intraluminal clot and flowing blood.

Intraprocedural data should be collected regarding

^mIt is recognized that standard treatment group parameters may best be represented by a range of reported values. TPEG and standard treatment groups of patients must have equivalent systemic risk factors and disease morphology and complexity.

ⁿPatient selection criteria will be based on device characteristics. However, all patients must be suitable candidates for standard operative repair of their aneurysm and must have appropriate indications for such a repair.

Table I. Important study criteria for each category of arterial lesion/location

<i>Study criteria</i>	<i>Infrarenal AAA tubular device</i>	<i>Infrarenal AAA with iliac aneurysm bifurcated device</i>	<i>Peripheral aneurysm tubular device</i>	<i>Traumatic arterial lesions</i>	<i>Aortoiliac occlusive disease</i>	<i>Femoropopliteal occlusive disease</i>	<i>Descending thoracic aorta</i>
Procedural death	++	++	+	+	+	+	++
Complications*							
Myocardial infarction	++	++	+	+	++	++	++
Other cardiac	++	++	+	+	++	++	++
Pulmonary	++	++	+	+	++	++	++
Renal failure	++	++	+	+	++	++	++
Bowel ischemia	++	++	—	—	++	—	++
Bowel obstruction	++	++	—	—	++	—	—
Procedural failure†	+	+	+	+	+	+	+
Leak	++	++	++	++	++	++	++
Device migration	++	++	++	++	++	++	++
Embolism	++	++	++	++	++	++	++
Thrombosis	++	++	++	++	++	++	++
Inadequate function‡	++	++	++	++	++	++	++
Limb loss	+	+	++	++	++	++	+
Paraplegia or paraparesis	+	+	—	—	—	—	++
Other§	++	++	+	+	+	+	+
Death from rupture	++	++	—	++	++	—	++
Conversion to standard open operation	++	++	++	++	++	++	++
Increase in aneurysm size	++	++	++	+	—	—	++
Lack of increase in aneurysm size	++	++	++	—	—	—	++
Graft patency	++	++	++	++	++	++	++
Graft enlargement (>25%)	++	++	+	+	+	—	++
Persistent flow in sac or branch artery	++	++	+	+	+	+	++
Normal flow without leak, twist, or migration	++	++	++	++	++	++	++

AAA, Abdominal aortic aneurysm; ++, primary criterion; +, secondary criterion; —, recorded but probably not relevant.

*Definitions provided in Table II.

†Inability to insert device.

‡Flow reduction without thrombosis.

§Infection, bleeding. Infection involving an endoluminal device is ++ in all categories.

the site of device placement, including that of the proximal and distal attachment, if appropriate, relative to the aorta/aneurysm; the relationship of the device, its stented and unstented portions, and its covered and uncovered portions to patent arteries; and the diameter and length of the stent(s) (when applicable) after deployment. Data should also include the length and diameter of the graft, the site and route of introduction, sheath configuration and diameters, blood loss, total fluoroscopy time, hematoma formation, and any problems associated with device insertion.

If balloons or stents other than those designated in the experimental protocol are used, the length, diameter, specifications, and manufacturer should be recorded along with inflation volume, time, and

pressure.^o Data on any associated procedure that is required, such as transluminal balloon angioplasty of the iliac arteries, placement of additional stents,^p covered stents,^p stented grafts,^p or arterial repair or thrombectomy should also be recorded. The type of anesthesia, medications required, the duration of the

^oA standardized delivery system should be used with each device being studied for a particular lesion in a particular location. Otherwise, stratification based on delivery system variation will be required. However, other balloons and material may be required during the implantation procedure or for management or treatment of complications, and all such details should be recorded.

^pIf these are investigational devices, their use could confuse the results of a TPEG trial. Such use of adjunctive investigational devices should be identified and results with them reported separately from other results obtained without them.

Table IIA. Definitions of systemic or organ-related complications

<i>Complication</i>	<i>Definition</i>
Myocardial infarction	Significant elevation of CPK-MB, appearance of new significant Q wave or loss of R waves
Other cardiac complication	
Arrhythmia	Requiring treatment with drugs, cardioversion or pacemaker
Congestive heart failure	Requiring tracheal intubation or ICU care
Pulmonary complication	Requiring tracheal reintubation, extension of ventilator support beyond 48 hours, ICU care beyond 3 days or return to ICU
Renal failure	Creatinine rise >30% or requiring dialysis
Bowel ischemia	Mucosal hemorrhage or requiring bowel resection or colostomy
Bowel obstruction	Requiring extended (>4 days) nasogastric intubation or laparotomy
Neurologic complications	
Stroke	New neurologic event lasting >24 hours
Transient ischemic attack	Neurologic event lasting <24 hours
Paraplegia or paraparesis	Lasting >24 hours
Limb loss	Major amputation at level of ankle or above

CPK-MB, Creatinine phosphokinase myocardial band; ICU, intensive care unit.

procedure, and a description or diagram of the procedure should be recorded, and a hard copy of the completion arteriogram should be kept on file.

Any procedural complications such as device twisting, leakage, misplacement, migration, or failure should be recorded along with the endovascular or operative maneuvers required to manage the complication. If device removal is required, the steps involved should be detailed along with the outcome of these corrective efforts. Complications involving the native arterial tree and their management should also be documented.

Early postprocedural data (7 to 10 days) should include the duration of hospitalization, a description of wound healing, an evaluation of device position, luminal patency, and complications (e.g., leakage, migration, kinking, twisting, or obstruction). These device-related evaluations should be based on conventional radiographic, CT, MRI, IVUS, or color-flow duplex imaging studies. Further evaluation by arteriography may be needed to exclude or further assess leakage, and ultrasonography may be used to demonstrate shrinkage and pulsatility of the aneurysm wall.

Complications from the procedure or the device should be described along with the steps taken to manage these complications and the outcome. During this early postprocedural period, all preprocedural data relative to renal and hematologic function, noninvasive evaluation of the peripheral circulation, aneurysm, and aortic structure should be repeated. This will permit an assessment of early device safety and efficacy.

Early mid term (6 months) postprocedural data should include all those parameters evaluated in the

first 7 to 10 days after device insertion and *must* include at least one adequate imaging technique (CT, IVUS, MRI, duplex ultrasonography, or arteriography) to evaluate luminal patency, device integrity and localization, aneurysm size and pulsatility, and freedom from leakage. All these parameters plus a hematologic and biochemical evaluation of organ function should be studied approximately 6 months after device insertion, although it is understood that many of these tests, particularly those that can be performed noninvasively or by blood sampling may be performed at more frequent intervals, specifically between 2 to 3 months after device insertion.

Late midterm (1 year) postprocedural data, including all those parameters outlined for early midterm evaluation, should be collected 1 year after device insertion. If a new device is as effective and as safe as standard operative aneurysm repair, according to the primary criteria in Table I, for 1 year, the manufacturer of that device may seek clearance to market and sell it for specific indications.²⁵

The same data including adequate imaging should be collected at 6- to 12-month intervals thereafter for the life of all patients receiving these devices. In that way, a determination can be made of long-term or *late postprocedural* (3 to 5 years) safety, efficacy, and effectiveness; and comparative performance of the device in relationship to standard aneurysm repair can be determined. With this information and the data regarding adverse device effects, it will be possible to determine whether the TPEG device should be used as preferential treatment for selected patients at high risk, for patients now subjected to standard surgical repair, or even for some smaller aneurysms not currently being treated.

Table IIB. Definition of device failures or complications

<i>Complication</i>	<i>Definition</i>
Device occlusion	Absence of flow through the device with or without intraluminal thrombosis
Stenosis	Device related lumen reduction in, proximal to, or distal to the device associated with a reduction in flow or pressure
Leak	Flow of blood outside the lumen of a device when all such flows should be contained within its lumen
Migration	Displacement of the device sufficient to be associated with another complication, e.g., occlusion, stenosis or leak
Embolism	Formation of thrombosis within the device with migration to a distal artery

Table III. Prerequisite information regarding risk factors

Cardiac function	Left ventricular ejection fraction History of myocardial infarction Presence of significant Q waves Arrhythmias Thallium persantine stress test abnormalities History of angina pectoris History of congestive failure History of diastolic blood pressure > 90 mm Hg or systolic pressure > 160 mm Hg History of diabetes
Renal function	Serum BUN Serum Creatinine
Pulmonary function	Arterial blood gases on room air FEV ₁ Chest radiogram abnormalities Decreased exercise tolerance
Hematological profile	CBC, platelet count, prothrombin time, partial thromboplastin time
Liver function	Serum albumin, bilirubin, SGOT, SGPT Prothrombin time History of cirrhosis, hepatitis
Local risk factors	History of previous operations Description of scarring and infections (past, present)

BUN, Blood urea nitrogen; *FEV₁*, forced expiratory volume in 1 second; *CBC*, complete blood count; *SGOT*, serum glutamic oxylactic transaminase; *SGPT*, serum glutamic pyruvic transaminase.

In addition, information will be obtained that will help to determine when the device should not be used or its use should be restricted to certain anatomic situations, and whether it should be considered for use in circumstances other than those provided by an unruptured infrarenal aortic aneurysm, such as anastomotic aneurysms, aortic aneurysms proximal to a previous aneurysm repair, ruptured aneurysms or infected aneurysms.

Abdominal aortic aneurysm (infrarenal) with iliac involvement or aneurysm(s)—bifurcated devices

TPEG repair of these aneurysms will require a bifurcated or branched device, although it is possible for some aortoiliac aneurysms to be repaired by a tubular TPEG device to revascularize one limb

supplemented by femorofemoral bypass and occlusion of the opposite common iliac artery by some means. (This type of procedure is considered to be a subgroup of the aneurysms in the previous section.)

In general the feasibility testing, the preprocedural, intraprocedural, early postprocedural, mid-term postprocedural, and late postprocedural data, and the design of comparative performance clinical trials will be similar to those outlined in the previous section addressing tubular devices for abdominal aortic aneurysms. The use of a bifurcated device may be more complicated and possess specific additional risks during device insertion and in the postprocedural period. With bifurcated devices specific information regarding the status and maintenance of perfusion in the internal and the external iliac arteries

should be recorded before and at the various intervals after device insertion. Information regarding possible continued flow into the aneurysm from the internal iliac arteries and the status of the colonic circulation after the procedure should also be obtained.

Peripheral aneurysm (femoral, popliteal, and others^a in comparably sized arteries) – tubular devices

In general, TPEG devices used to treat these lesions will have an expanded internal diameter from 6 to 16 mm. One possible design will have an attachment device at both ends, although in others a graft will be attached at one end with an endoluminally placed device, and arterial continuity will be established at the other end by performing an open suture anastomosis. Other effective designs, such as grafts supported throughout their entire length, may also be developed.

Feasibility testing with these devices will be performed on patients who have indications for operative repair and who satisfy the general requirements for feasibility testing already outlined. These feasibility tests for aneurysms in these specific locations^f should be *carried out in at least 10 patients* monitored for 6 months to demonstrate reasonable safety and efficacy with regard to the primary criteria specified in Table I. Adequate *preprocedural data* should be collected to characterize the aneurysm, the distal circulation (ABI), and the patients' systemic and local risk factors (Table III).

Intraprocedural, early, and early midterm postprocedural data should include a description of the experimental device, the diameter and length of its components, a description of the placement procedure including the route of access, the anesthesia, a description of the insertion procedure, the location of the device and its components (supplement with diagram), any procedural complications or mishaps, the need to perform any surgical or interventional reparative procedure to deal with problems that were encountered, blood loss, and length of hospital stay.

^aThese include isolated iliac, subclavian, and carotid artery aneurysms in patients with appropriate proximal and distal arterial anatomy for device fixation.

^fIt may also be possible to combine results of a given device used for similar lesions in several different locations to demonstrate feasibility with smaller numbers of device implantations. In such combined feasibility studies, data will have to be stratified by location and emphasis should be placed on the "worst case" or most difficult location to access and treat. Similar considerations may also apply to comparative performance testing of devices for treating peripheral aneurysms in these locations.

Data collected at 6 months should include repetition of preprocedural studies that are required to demonstrate exclusion of the aneurysm from the circulation and maintenance of luminal continuity and distal arterial circulation without device migration, leakage, or other defects. These data should include ABI, duplex ultrasonography or CT scanning, MRI, or arteriography.

Satisfactory completion of feasibility testing should be followed by *comparative performance testing*. Data similar to that for the feasibility testing should be collected. Postprocedural data collection should take place at 3, 6, 12, 18, and 24 months. TPEG devices proposed for *femoral aneurysms* or other peripheral aneurysms should be compared with standard prosthetic (PTFE or polyester fabric) or autologous grafts where appropriate. Several cooperating centers may be required to accumulate a sufficient group of patients to enable a statistically and scientifically valid judgment to be made regarding *safety* and *efficacy* (as described earlier) and *effectiveness* (i.e., prevention of embolization, limb loss, and aneurysm rupture) for at least 1 year.

If the comparative performance trials demonstrate that the TPEG performs as well as or better than operatively placed grafts, the manufacturer may seek clearance to market and sell the device. However, the patients from the initial study should be monitored until long-term (3 to 5 years) data are available.

Traumatic arterial lesions (false aneurysms, arteriovenous fistulas, mural injuries)

The TPEG devices for treatment of these injuries will generally have an expanded internal diameter of 6 to 25 mm depending on the artery that is injured and will probably consist of a 2 to 6 cm-long attachment device covered except for 5 to 10 mm at its ends by a tube of polyester fabric, expanded PTFE, or some other material.^g These devices should be deployed to cover the defect in the arterial wall (false aneurysms or arteriovenous fistulas) or to reinforce the arterial wall and fix intimal flaps (mural injuries). Initially these devices will probably only be used to treat arterial injuries less than 4 cm in length because it is likely that longer injuries will be associated with sufficient soft tissue damage and internal or external bleeding and that standard operative repair will be

^gThis is one example. Other possible designs may be developed, e.g., a stent-like material incorporated uniformly within a graft matrix or some other combination of fixation device and graft.

required. However, it is conceivable that longer injuries could be treated by TPEGs.

After appropriate bench and animal testing for prosthetic grafts that might be used in comparable locations, human *feasibility testing* should be carried out in patients who would otherwise require a standard operative repair and whose conditions are stable enough to permit preprocedural angiographic definition of the vascular injury and the distal arterial circulation. Ideally, separate feasibility studies should be performed for injuries of the aorta and innominate artery, the iliac and common femoral arteries, the subclavian and axillary arteries, the superficial femoral and popliteal arteries, and the carotid and vertebral arteries. In each of these five arterial systems,[†] these feasibility studies should show that the device can safely be implanted in *10 patients* and can maintain a satisfactory repair of the lesion with preservation of luminal continuity without distal embolization for at least *6 months*.

Preprocedural data should be collected to characterize the location and length of the arterial injury, the cause of the injury (blunt trauma, gunshot or knife wound, or iatrogenic or other injury), the nature of the injury, and associated injuries. *Intraprocedural* data should include the diameter and length of the graft and the attachment device, a description of the placement procedure, the route of access, whether the device was inserted percutaneously or by open operation, the location of the device and its components (supplement with diagram), any procedural complications or mishaps, the need to perform surgical or catheter-based corrective procedures, procedural blood loss, and length of hospital stay. *Early and 6-month postprocedural* data should be similar to those already described for other TPEG devices and should demonstrate luminal continuity, correction of the arterial defect, maintenance of the distal circulation and freedom from device migration, leakage, embolization, or aneurysm formation.

Satisfactory completion of feasibility testing in each location or system should be followed by *comparative performance testing* in each or a combina-

tion of the major arterial systems described above, recognizing the limited number of suitable patients available for inclusion in these trials. Ideally in each of these systems, TPEG device repairs should be characterized with regard to the criteria listed in Table I so that comparisons can be made with similar data for operative repair of similar lesions. The procedural and postprocedural data collected should be similar to those already described.

If the TPEG device proves equivalent or superior to standard repair for *1 year*, the manufacturer may seek clearance to market and sell the device for these specific indications. Although the increased simplicity and minimally invasive nature of treating traumatic injuries of these arteries with nonautologous TPEGs is attractive, such treatment should be validated by patency studies extending at least to 5 years. Therefore all patients in these studies should continue to be evaluated every 6 months for *5 years* with use of the same parameters already described. In this way, the long-term effectiveness, as well as the limitations and late complications of TPEGs can be determined. Particular attention should be directed toward the patency results of these short devices in small-diameter arteries such as the superficial femoral and popliteal where the long-term patency of prosthetic grafts may be poor.

Distal aorta and iliac artery (common and external) occlusive disease

TPEGs that will be used to treat these lesions will probably have an expanded internal diameter from 6 to 20 mm and either an attachment device at both ends of a tubular graft or a proximal fixation system and a distal suture anastomosis, although other configurations may be developed. A distal suture anastomosis may be necessary if the anatomic situation demands that the graft terminate at a point where two important patent artery branches originate (e.g., the junction of the superficial and deep femoral arteries). The requirements for bench and animal testing for the grafts used in these devices should be similar to those required for standard grafts used in these locations.²⁴⁻²⁶ However, because the grafts will be placed within dilated or recanalized occluded arteries, it is possible that they may not need to have the same structural and porosity specifications as standard bypasses, but evidence supporting the safety of modified or new grafts should be presented.

Feasibility testing of these devices should be performed on patients who have indications for operative repair but who may also have a major systemic or local contraindication to such an opera-

[†]However, because these are uncommon lesions, it may be necessary to combine results of a given device used in several different locations to demonstrate feasibility with smaller numbers of device implantations. In such combined studies data will have to be stratified by location and emphasis must be placed on the "worst case" or most difficult location to access and treat. Because they involve arteries supplying the brain, devices for use in the carotid and vertebral arteries should be evaluated separately. Similar considerations may apply to comparative performance testing of devices for treating arterial trauma in these locations.

tion. Contraindications to standard operative bypass grafting include severe heart or lung disease or other systemic disorders that preclude general or major regional anesthesia or factors such as scarring or infection that would make an open arterial operation excessively difficult or dangerous. In addition, the lesions may be suitable for treatment by conventional percutaneous balloon angioplasty (PTA) with or without endoluminal stent placement depending on the length or complexity of the occlusive and stenotic process. These feasibility tests should be carried out in at least 10 patients who are monitored for 6 months to demonstrate reasonable safety and efficacy. Adequate *preprocedural data* should be collected to characterize the nature and extent of the patients' occlusive disease (arteriography), the status of the distal circulation (ABI, pulse volume recordings [PVR]), and the patients' systemic and local risk factors (Table III). *Intraprocedural data* should include the diameter and length of the graft(s) and the attachment systems, a description of the placement procedure including the route of access and whether it was performed open or percutaneously, unilaterally or bilaterally, the location of the graft(s) and stent(s) within the arterial tree (supplemented with diagram), a description of any procedural complications and the catheter-directed or surgical techniques required to correct the problem, and the length of hospital stay. *Postprocedural data* to demonstrate 6-month safety and efficacy should include repetition of the preprocedural studies (ABI, PVR, arteriography, and duplex scanning) to document graft patency, improved distal perfusion and freedom from leakage, collateral or branch occlusion, or device migration. These data may be supplemented, when necessary, by imaging studies such as plain radiography, CT scanning, MRI, and IVUS.

Satisfactory completion of feasibility testing should be followed by *comparative performance testing* in which the new TPEG device is compared, with standard prosthetic bypass grafts (aortobifemoral, axillofemoral, iliofemoral, or femorofemoral) and against PTA alone or supplemented by stents. Because of the variability of the disease in the aortoiliac segment, these will be complex studies to conduct. Many patients will have to be enrolled to eliminate or define confounding variables. It is likely that these studies will have many arms and will require multiple collaborating centers.

In these studies, adequate data should be collected on risk factors, the degree of ischemia, and the arterial disease, as well as the local factors enumerated previously to be sure that the test groups receiving the

new TPEG treatment and the standard therapy groups are well matched except for the treatment used. Follow-up and data accumulation (with the criteria outlined in Table I) on these patients should determine 1-year results and then be continued to determine long-term (3 to 5 years) safety, efficacy, effectiveness, and durability. In addition, these studies might provide an assessment of the relative effects of these new devices and standard treatments on the progression of atherosclerotic disease, and of how device complications and failures should best be managed.

Femoropopliteal occlusive disease

The TPEGs that will be used to treat these lesions will most likely have an expanded internal diameter from 4 to 8 mm. They may have an attachment system at one or both ends of a tubular graft, although the distal end may not require such a system, and either the proximal or distal anastomosis may be performed in the standard open-sutured fashion, or a stentlike component may be incorporated in a graft matrix. These devices may be insertable percutaneously or via an open arteriotomy. The requirements for bench and animal testing are similar to those already described for iliac TPEG devices.

Feasibility testing of these devices for femoropopliteal occlusive disease should be carried out on patients who have indications for operative vein or prosthetic bypass and who also may have a major contraindication to such an operation. In addition, the lesions may be suitable for a standard PTA by virtue of their length or complexity. Data collection before, during, and after the procedures up to 6 months should parallel those described in the "Distal Aorta and Iliac Artery (Common and External) Occlusive Disease" section and should be obtained on at least 10 patients to demonstrate safety and efficacy of the device for that length of time.

Satisfactory completion of feasibility testing can then be followed by *comparative performance testing* as described above for iliac occlusive lesions.¹⁴ Because of the multiple variables in risk factors, degree of ischemia, and arterial disease in this setting, adequate numbers of patients will have to be studied so that confounding variables can be eliminated. It is therefore likely that these studies will also require multiple

¹⁴TPEG results should be compared with standard surgical vein and prosthetic bypasses and possibly with PTA and PTA with stents (if the latter are shown to be safe and effective) in groups of patients suitable for treatment with PTA with or without stents.

collaborating centers and will have several arms. One obvious study group would be patients who do not have a useable autologous vein so that the performance of a TPEG procedure can be compared with that of a standard prosthetic graft. Data collection should permit evaluation of safety, efficacy, effectiveness, and durability of the new device at 1 year and ultimately after 4 to 5 years, which should allow valid comparisons with the more traditional operative and balloon angioplasty procedures, as well as determination of the precise indications and contraindications for use of these TPEG devices.

Descending thoracic aorta

The TPEG devices that will be used to treat lesions in this location will have expanded external diameters up to 45 mm or more. They may be comprised of a single or multiple contiguous stents covered by a graft, two separate stents or attachment systems at each end of a tubular graft or have some other design. They may be used to treat acute or chronic aortic dissections, degenerative atherosclerotic aneurysms, traumatic or postoperative false aneurysms, ulcerating mural lesions, intramural hematomas, and possibly other lesions. They will probably be inserted in a fashion similar to devices used to treat infrarenal aortic aneurysms.

The requirements for bench and animal testing, as well as feasibility and comparative performance trials will be similar to those already described for abdominal aortic aneurysm devices. However, because several pathologic processes will be treated in the thoracic aorta, it will probably not be feasible to perform separate trials on each before marketing approval for general clinical usage is requested.

Imaging of thoracic lesions with transesophageal echo and with Doppler color-flow studies may be used to supplement the preprocedural and postprocedural evaluations recommended for abdominal aortic aneurysms.²⁸ Experience to date dictates that TPEG procedures on the thoracic aorta be performed in a procedural room in which the following techniques are available: general anesthesia with endobronchial intubation, pulmonary artery catheterization, and, in some instances, the equipment and staff to perform emergency operation with complete cardiopulmonary bypass. When the latter may be required, the participation of a cardiothoracic surgeon is mandatory.

TPEG REGISTRY RECOMMENDATIONS

To maximize the knowledge gained from the widespread early experiences in the developing field

of TPEGs, the data from all feasibility and comparative performance trials that are conducted should be collected, stored, and analyzed by a central databank or registry. Submission of all clinical trial data to such a registry should be mandatory and a requirement for obtaining marketing approval. Such a registry is being developed by the same Endovascular Graft Committee that wrote these guidelines. Additional information about this TPEG registry can be obtained from K. Wayne Johnston, MD, Toronto General Hospital, Toronto, Ontario, Canada.

TRAINING REQUIREMENTS FOR USAGE OF TPEGs

For initial clinical studies with each device, principal investigators will need to work with the manufacturer to develop appropriate training programs for all investigators. The teams that will be involved in the use of a given TPEG device must include an experienced vascular surgeon (or cardiothoracic surgeon for procedures on the thoracic aorta) and interventional radiologist, both of whom devote a major portion (>50%) of their activity to the management of noncardiac vascular disease.^w The training program must include adequate large animal experience (or mock circulatory model experience) to ensure technical proficiency with the usage of the device being evaluated. Although it is recognized that good animal models for human aneurysmal and occlusive disease do not exist, animal (or model) experience should be obtained by placing the device under fluoroscopic control in an anesthetized animal (or model) in arteries large enough to approximate those that will be encountered in human patients.

When individuals or teams have had this initial animal or model experience and then implanted the TPEG device in at least *three patients* with acceptable results, they may qualify as *instructors* for other individuals who desire to perform investigational procedures with the device in question. The individuals or teams being qualified in this way must possess the full knowledge of vascular disease and all its treatment methods and the requisite surgical and catheter-guidewire skills and experience, as already outlined. They must participate as assistants in at least *three procedures* that use the device and that are being

^wSeparate training and credentialing guideline documents for individuals who can perform vascular surgery and endovascular procedures have been prepared by various specialty organizations.¹⁸⁻²³ The general principles expressed in these documents should also apply to this guideline document.

carried out by the individual or group who are serving as instructors. These background and training requirements apply to individuals or teams at other centers wishing to join an ongoing comparative clinical testing protocol.

REQUIREMENTS FOR FACILITIES IN WHICH TPEGs WILL BE USED CLINICALLY

Although it is probable that some of these devices may ultimately be suitable for safe and reliable percutaneous introduction,^{4,5} experience to date indicates that open vascular operations are required or may be required as a part of many TPEG insertion procedures or to treat complications or adverse events that may occur.^{1,6-15} Accordingly, it is mandatory that facilities in which these procedures are performed be suitable for the performance of open arterial operations and catheter-directed fluoroscopically guided techniques with high-quality imaging. Such facilities can take one of two forms. A standard operating room or comparable location may be equipped to perform open arterial operations, digital imaging fluoroscopy, and arteriography, and catheter-guidewire manipulations at several levels of the arterial tree. There are a number of ceiling- and floor-mounted digital fluoroscopy/arteriography units and movable radiolucent operating tables that are ideally adapted to the performance of these procedures in an operating room setting. However, it is also possible to perform them adequately with an electrically operated radiolucent movable operating table and C-arm portable digital imaging and fluoroscopy with hard copy and videotape recording capability and preferably with last image hold and roadmapping. The procedural room should be equipped with conventional (525 line) or high-resolution (1000+ line) imaging chains capable of resolving at least 3.3 line pairs per mm in the 9-inch image intensifier. The image intensifier should have a high contrast ratio (20:1), provide manual collimation, and be of high conversion gain. The room should also be equipped with a power injector for adequate digital angiography.

Alternatively, a standard arteriography suite equipped for digital imaging fluoroscopy and catheter-guidewire technologies can be modified to permit emergency sterile open operations according to standards of the Association of Operating Room Nurses.³³ For procedures in which devices will be placed in the abdominal or thoracic aorta or iliac or visceral arteries, patient safety considerations, and the possible need to deal with emergency compli-

cations mandate that they be performed in a room that is fully equipped and staffed with appropriate nursing and anesthesia personnel so that major vascular operations can be performed safely and expeditiously if required. For thoracic aortic procedures, perfusionists and equipment for instituting total cardiopulmonary bypass must also be immediately available.

In the future, different combinations of various imaging modalities other than fluoroscopy may prove equally effective and safe for the deployment of TPEGs and may be substituted for those described above to facilitate TPEG device insertion and evaluation in different treatment environments.

RADIATION SAFETY REQUIREMENTS

Federal regulations regarding maximum fluoroscopic radiation exposure rates must be followed. If high-level control (HLC) fluoroscopy is used, activation of this mode must be accompanied by a continuous audible signal and the output of the x-ray tube in HLC fluoroscopy should be closely monitored and measured and should not exceed 20 R/min. A cumulative monitor of fluoroscopy time should be present, and the time should be recorded for each patient. The procedure room should meet the radiation protection standards of the National Council on Radiation Protection,³⁴⁻³⁷ and the workers should have awareness of the safety standards of the International Commission of Radiation Protection. All personnel within the room should wear lead aprons, and individual state regulations regarding personnel dosimetry should be followed. Quality control charts should be maintained on the radiography equipment, and arrangements should be made for their routine maintenance. All quality control data should be reviewed by a medical physicist at least annually.³⁷ The procedural room should have a safe, electrical primary wiring system and proper electrical isolation of all equipment attached to the patient. With the addition of angiographic equipment and the presence of catheters within the vascular system, there should be periodic inspection of the electrical system, which should have equipotential hardwired grounding. Electrical safety checks should be reviewed at least annually by a qualified medical physicist.

MODIFICATIONS OF THESE GUIDELINES

The developmental paths of TPEGs, the optimal technology, their ultimate value, the complications of their insertion, their impact on various arterial disease

processes, and the various modifications that may be introduced are presently unknown. It is therefore probable that these guidelines will evolve and change to encompass new treatment developments. Accordingly, future modifications and refinements of this document should be made as needed by the *Endovascular Graft Committee* of the Joint Council of the Society for Vascular Surgery and the North American Chapter of the International Society for Cardiovascular Surgery and the Society of Cardiovascular and Interventional Radiology.

REFERENCES

1. Parodi JC, Palmaz JC, Barone HD. Transfemoral intraluminal graft implantation for abdominal aortic aneurysms. *Ann Vasc Surg* 1991;5:491-9.
2. Laborde JC, Parodi JC, Clem MF, et al. Intraluminal bypass of abdominal aortic aneurysm: feasibility study. *Radiology* 1992;184:185-90.
3. Chuter TAM, Green RM, Ouriel K, Fiore W, DeWeese JA. Transfemoral endovascular aortic graft placement. *J VASC SURG* 1993;18:185-97.
4. Cragg AH, Dake MD. Percutaneous femoropopliteal graft placement. *Radiology* 1993;187:643-8.
5. Marin ML, Veith FJ, Panetta TF, et al. Percutaneous transfemoral stented graft repair of a traumatic femoral arteriovenous fistula. *J VASC SURG* 1993;18:298-301.
6. Parodi JC, Barone HD, Schonholz C, Marin ML, Panetta TF, Cynamon J, Veith FJ. Endovascular insertion of balloon expandable stented grafts to treat peripheral arterial lesions: initial experience in man. *Proceedings of the XXI World Congress of the International Society for Cardiovascular Surgery*, Sept. 13-15, 1993;Lisbon, Portugal.
7. Marin ML, Veith FJ, Panetta TF, et al. Transfemoral stented graft treatment of occlusive arterial disease for limb salvage: a preliminary report [Abstract]. *Circulation* 1993;88:I-11.
8. Marin ML, Veith FJ, Panetta TF, et al. Transfemoral endoluminal stented graft repair of popliteal artery aneurysm. *J VASC SURG* 1994;19:754-7.
9. May J, White G, Waugh R, Yu W, Harris JM. Transluminal placement of a prosthetic graft-stent device for treatment of subclavian aneurysm. *J VASC SURG* 1993;18:1056-9.
10. Volodos NL, Karpovich IP, Troyan VI, et al. Clinical experience of the use of self-fixing synthetic prostheses for remote endoprosthetics of the thoracic and abdominal aorta and iliac arteries through the femoral artery and as intraoperative endoprosthesis for aorta reconstruction. *Vasa* 1991;33:93-5.
11. Marin ML, Veith FJ, Panetta TF, et al. Transluminally placed endovascular stented graft repair for arterial trauma. *J VASC SURG* 1994;20:466-73.
12. Marin ML, Veith FJ, Cynamon J, et al. Transfemoral endovascular stented graft treatment of aorto-iliac and femoropopliteal occlusive disease for limb salvage. *Am J Surg* 1994;168:156-62.
13. Parodi JC. Endovascular repair of abdominal aortic aneurysms. *Adv Vasc Surg* 1993;1:85-106.
14. Moore WS, Vescara CL. Repair of abdominal aortic aneurysm by transfemoral endovascular graft placement. *Ann Surg* 1994;220:331-41.
15. White GH, Weiyun Y, May J, Stephen MS, Waugh RC. A new nonstented balloon-expandable graft for straight or bifurcated endoluminal bypass. *J Endovasc Surg* 1994;1:16-24.
16. Scott RAP, Chuter TAM. Clinical endovascular placement of bifurcated graft in abdominal aortic aneurysm without laparotomy. *Lancet* 1994;343:413.
17. Yusuf SW, Baker DM, Chuter TAM, Whitaker SC, Wenham PW, Hopkinson BR. Transfemoral endoluminal repair of abdominal aortic aneurysm with bifurcated graft. *Lancet* 1994;344:650-1.
18. Moore WS, Treiman RL, Hertzner NR, Veith FJ, Perry MO, Ernst CB. Guidelines for hospital privileges in vascular surgery. *J VASC SURG* 1989;10:678-82.
19. String ST, Brener BJ, Ehrenfeld WK, et al. Interventional procedures for the treatment of vascular disease: recommendations regarding quality assurance, development, credentialing criteria, and education. *J VASC SURG* 1989;9:736-9.
20. Spies JB, Bakal CW, Burke DR, et al. Guidelines for percutaneous transluminal angioplasty. *Radiology* 1990;177:619-26.
21. Levin DC, Becker GJ, Dorros G, et al. Training standards for physicians performing peripheral angioplasty and other percutaneous peripheral vascular interventions. *Circulation* 1992;86:1348-50.
22. White RA, Fogarty TJ, Baker WH, Ahn SS, String ST. Endovascular surgery credentialing and training for vascular surgeons. *J VASC SURG* 1993;17:1095-102.
23. Spittell JA, Creager MA, Dorros G, et al. Recommendations for peripheral transluminal angioplasty: training and facilities. *J Am Coll Cardiol* 1993;21:546-8.
24. Standards for vascular graft prostheses. Arlington, Va.: The Association For The Advancement Of Medical Instrumentation; 1986. ANSI/AAMI VP20.
25. Abbott WM, Callow A, Moore W, Rutherford R, Veith FJ, Weinberg S. Evaluation and performance standards for arterial prostheses. *J VASC SURG* 1993;17:746-56.
26. Guidance For The Preparation of Research and Marketing Applications For Vascular Graft Prostheses (Draft). Rockville, Md.: Prosthetic Devices Branch, Division of Cardiovascular, Respiratory and Neurological Devices, Office of Device Evaluation; 1993. US Dept HHS, Public Health Service, Food and Drug Administration, Center for Devices and Radiological Health.
27. Guidance For The Submission of Research and Marketing Applications For Interventional Cardiology Devices: PTCA Catheters, Atherectomy Catheters, Lasers, Intravascular Stents (Draft). Rockville, Md.: Interventional Cardiology Devices Branch, Division of Cardiovascular Respiratory and Neurology Devices, Office of Device Evaluation; 1993. US Dept HHS, Public Health Service, Food and Drug Administration, Center for Devices and Radiological Health.
28. Moon MR, Dake MD, Pelc LR, Liddell R, Castro LJ, Mitchell RS, Miller DC. Intravascular stenting of acute experimental type B dissections. *J Surg Res* 1993;54:381-8.
29. Balko A, Piaseck GS, Shah DM, Carney WI, Hopkins RW, Jackson BT. Transfemoral placement of intraluminal polyurethane prosthesis for abdominal aortic aneurysm. *J Surg Res* 1986;40:305-9.
30. Mirich D, Wright KC, Wallace S, et al. Percutaneously placed endovascular grafts for aortic aneurysms: feasibility study. *Radiology* 1989;170:1033-7.
31. Hollier LH, Taylor LM, Ochsner J. Recommended indications for operative treatment of abdominal aortic aneurysms. *J VASC SURG* 1992;15:1046-56.
32. Sapirstein W, Albert S, Callahan TJ. The role of clinical trials

in the Food and Drug Administration approval process for cardiovascular devices. *Circulation* 1994;89:1900-2.

33. Standards of Recommended Practices. Denver: Association of Operating Room Nurses. 1993.
34. National Council on Radiation Protection and Measurements. Recommendations on the limits of exposure to ionizing radiation. Bethesda: NCRP; 1987. NCRP report no. 91.
35. National Council on Radiation Protection and Measurements. Implementation of the principal of as low as reasonably achievable for medical and dental personnel. Bethesda: NCRP; 1990. NCRP report no. 107.
36. Federal Radiation Protection Guidance For Occupational Exposure. *Federal Register* January 27, 1987;52:2822-35.
37. National Council on Radiation Protection and Measurements. Quality assurance: diagnostic imaging. Bethesda: NCRP; 1988. NCRP report no. 99.

Submitted Oct. 25, 1994; accepted Dec. 23, 1994.

APPENDIX

The Endovascular Graft Committee is an Ad Hoc Conjoint Committee of the Joint Council of the Society for Vascular Surgery and the International Society for Cardiovascular Surgery, North American Chapter and the Society of Cardiovascular and Interventional Radiology. The Committee includes representatives from the Food Drug Administration and the National Heart, Lung and Blood Institute, National Institutes of Health.

Committee members: Jerry Goldstone (Current Chairman), Brian Thiele (Past Chairman), William M. Abbott, Dorothy Abel, Michael D. Dake, Paul Didisheim, Calvin B. Ernst, Thomas J. Fogarty, K. Wayne Johnston, Barry T. Katzen, D. Craig Miller, Wesley S. Moore, George Sopko, Arina van Breda, Frank J. Veith, Rodney A. White, James S. T. Yao, Jacob Cynamon, Richard H. Dean, Richard M. Green, Larry H. Hollier, Eric Martin, Juan C. Parodi, Julio Palmaz, Robert Vogelzang, and Robert B. Rutherford.

The Society for Vascular Surgery and the International Society for Cardiovascular Surgery: Frank J. Veith, William M. Abbott, James S. T. Yao, Jerry Goldstone, Rodney A. White, Calvin B. Ernst, Thomas J. Fogarty, K. Wayne Johnston, Wesley S. Moore, Robert B. Rutherford, D. Craig Miller, Brian Thiele, Richard M. Green, Richard H. Dean, Juan C. Parodi, and Larry H. Hollier.

The Society of Cardiovascular and Interventional Radiology: Michael D. Dake, Arina van Breda, Barry T. Katzen, Jacob Cynamon, Eric Martin, Julio Palmaz, and Robert Vogelzang.

The Food and Drug Administration: Dorothy Abel.

The National Heart, Lung and Blood Institute, National Institutes of Health: George Sopko and Paul Didisheim.

AVAILABILITY OF JOURNAL BACK ISSUES

As a service to our subscribers, copies of back issues of JOURNAL OF VASCULAR SURGERY for the preceding 5 years are maintained and are available for purchase from the publisher, Mosby-Year Book, Inc., at a cost of \$10.00 per issue. The following quantity discounts are available: 25% off on quantities of 12 to 23, and one third off on quantities of 24 or more. Please write to Mosby-Year Book, Inc., Subscription Services, 11830 Westline Industrial Drive, St. Louis, MO 63146-3318, or call (800)453-4351 or (314)453-4351 for information on availability of particular issues. If unavailable from the publisher, photocopies of complete issues are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or call (313)761-4700.